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EXAMINER	
ORWIG, KEVIN S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,547	DAVIS ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *Jul. 28, 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-15 are currently pending. Claims 1-13 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 14 and 15 are withdrawn from consideration.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13, drawn to a skin dressing.

Group II, claim 14, drawn to a method of making a skin dressing.

Group III, claim 15, drawn to a method of using a skin dressing.

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." Moreover, as stated in Rule 13.2 PCT, Unity of Invention is satisfied "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or

corresponding special technical features." The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art so linked as to form a single general inventive concept."

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature among the inventions is a skin dressing comprising at least 25% by weight of the polymer material (i.e. claim 1). However, Groups II and III do not require the dressing of claim 1. For example, the method of making a dressing (i.e. Group II) does not produce a dressing comprising at least 25% by weight of the polymer material. Likewise, the method of using a dressing (i.e. a method of treating skin, Group III) does not require the use of a dressing comprising at least 25% by weight of the polymer material. The dressing of instant claim 1 is not a technical feature shared by the Groups and thus is not a special technical feature as defined under PCT Rule 13.2, Part I (b). Thus, the Groups do not share a common special technical feature and are subject to restriction.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Paul Kokulis on Feb. 12, 2009 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided in English. The IDS indicated that a translation of the abstract for DE 4026153 was provided, but none was found.

Claim Objections

Claim 13 is objected to because of the following informalities: the phrase "the or" in line two of the claim should be deleted.

Appropriate correction is required.

Priority

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIS (WO 03/090800; Published Nov. 6, 2003; 3rd foreign reference on IDS dated Jul. 28, 2006) in view of MUNRO (U.S. 2002/0037270; Published Mar. 28, 2002).

1. Davis discloses hydrated hydrogel skin/wound dressings comprising an oxidoreductase enzyme, particularly glucose oxidase, wherein the enzymes are in hydrated condition (title; abstract). Davis teaches that separate hydrogels (e.g.

hydrogel layers, such as an upper and lower layer) may be used (bottom of page 9 to top of page 10). Davis teaches that the dressing may include a substrate for the oxidoreductase enzyme (e.g. a source of glucose for glucose oxidase) (page 7, last paragraph to top of page 8; last paragraph on page 10). This substrate may be located in various positions within the layers of the patch (last paragraph on page 11; 1st paragraph on page 13; last paragraph on page 16; claims 12, 14, and 22). Davis teaches that each hydrated hydrogel conveniently comprises hydrophilic polymer material (1st sentence on page 6) and teaches the use of at least 10% by weight of the polymer material (page 6, 3rd paragraph). Furthermore, Davis teaches the use of poly 2-acrylamido-2-methylpropane sulphonic acid (poly-AMPS) as the hydrophilic material (bottom of page 8 to top of page 9; bottom of page 13) and discloses an embodiment wherein the dressing comprises 20% by weight AMPS. Thus, the only difference between Davis an instant claims 1 and 2 is the limitation that the hydrogels comprise at least 25% by weight of the polymer material.

2. As noted above, Davis teaches the use of at least 10% by weight hydrophilic polymer and embodies dressings with 20% by weight hydrophilic polymer. Additionally, Davis teaches that using a gel with a high concentration of hydrophilic polymer material, the gel can function particularly effectively to take up water in the use of the dressing (e.g. from serum exudates while in contact with a wound) (last paragraph of page 6 to top of page 7). Davis further teaches that the water-absorbing gel may utilize an increased concentration of hydrophilic substance, which may be the actual gel-forming polymer material itself, for the purpose of absorbing water (page 8, last paragraph).

Thus, the ordinary artisan would have been motivated to use higher concentrations, for example at least 30%, of the hydrophilic polymer to increase the capacity of the dressing to absorb water or wound exudate fluid.

3. Furthermore, the use of higher amounts of hydrophilic polymer materials for hydrogel wound dressings was known in the art at the time of the invention. For example, Munro discloses wound dressings comprising hydrogel compositions having bioadhesive properties (paragraph [0001]). Munro teaches that the polymers used in the hydrogel may include water soluble polymers such as poly(2- acrylamido-2-methylpropane-sulphonic acid) or one of its salts and its copolymers (paragraph [0054]), which is a preferred polymer in Davis' disclosure. Munro teaches that the hydrogels of the invention most preferably include from 25-70% by weight of the polymeric component (paragraphs [0032] and [0036]).

4. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include at least 25% hydrophilic polymer material in the hydrogels of Davis, to provide a highly water absorbing dressing. One would have had a high expectation of success in doing so since Davis suggests amounts higher than 10% and at least 20%. Further, it is well within the skill of the ordinary artisan to adjust the amounts of dressing components that are taught in the art to be variable. Thus, claims 1-4 and 11-13 are obvious over Davis and Munro.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA)

1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Munro as applied to claims 1-4 and 11-13 above, and further in view of BARROWS (U.S. 5,372,802; Issued Dec. 13, 1994) and MUNRO (WO 01/96422; Published Dec. 20, 2001) (hereinafter WO '422).

5. The teachings of Davis and Munro are presented *supra*. Davis does not teach the use of zinc ions in the dressings. Davis does not directly teach the use of ammonium poly-AMPS.

6. Davis specifies that polyAMPS or salts thereof as described in WO '422 are suitable hydrophilic polymeric materials for use in the hydrogel dressings of the invention (page 6, 4th line of top paragraph; bottom of page 8 to top of page 9). WO '422, to which Davis makes reference, discloses methods for making hydrogel wound dressings (abstract; 1st paragraph on page 1). WO '422 teaches that preferable monomers of the hydrophilic hydrogel material include ammonium and sodium salts of AMPS. Davis teaches that mixtures of hydrophilic polymer materials may be used in a

gel (middle of page 6), and further teaches the preparation of a series of hydrogels having different concentrations of hydrophilic material (top of page 26).

7. Thus, the ordinary artisan would have an expectation that some optimization of the types and amounts of the hydrophilic polymer component of the gel would be required to obtain the most suitable hydrogel structure for the dressing. Further, the artisan would be guided by Davis' teachings regarding the use of polyAMPS and its salts, and the concentrations thereof as discussed above. It is noted that there is no evidence of record regarding the criticality of the instantly claimed percentages. Thus, in the absence of evidence to the contrary, it would have been routine optimization for the artisan to vary the amounts of polyAMPS salts, which were taught in the art, to arrive at the most suitable combination, guided by the teachings of Davis and WO '422. Thus, claims 5-8 are obvious over Davis, Munro, Barrows, and WO '422.

8. Davis teaches that the glucose (i.e. the substrate for glucose oxidase) is typically present in an amount up to about 25% by weight of the dressing (page 11, top paragraph). Davis discloses an embodiment wherein the lower hydrogel layer includes 20% glucose. The enzyme-containing dressings disclosed by Davis provide antimicrobial benefits to skin or a wound due to the action of the oxidoreductase (e.g. glucose oxidase) on its substrate (e.g. glucose) to produce hydrogen peroxide (last two paragraphs on page 4). One of ordinary skill in the art would readily recognize from this teaching that the availability (i.e. the amount) of glucose correlates with the amount of hydrogen peroxide generated. Thus, the amount of glucose is clearly a result effective variable that the ordinary artisan would be motivated to optimize in the dressing

compositions depending on the particular application and intended length of time for its use. For instance, dressings for more serious or chronic wounds might require more glucose to achieve a longer period of hydrogen peroxide generation than those intended for minor wounds requiring less hydrogen peroxide. The artisan would initially be guided by the range of glucose taught by Davis of up to 25%. Thus, an artisan would have optimized the glucose content in the lower hydrogel layer per the intended use of the particular dressing, and a value of 5% glucose would have been *prima facie* obvious based on Davis' guidance, absent evidence to the contrary. Claims 6 and 7 are obvious over Davis and Munro.

9. Davis teaches the use of iodide ions for the purpose of reacting with hydrogen peroxide to produce molecular iodine, which is a known antimicrobial (last paragraph on page 4). Davis teaches that each gel may contain various reagents including a source of iodide ions (middle of page 7). Additionally, Davis teaches that two gels may be used in the dressing, the outer of which contains the oxidoreductase enzyme, and the inner of which contains the reactive antimicrobial species (1st full paragraph on page 10). One of ordinary skill would understand that iodide ions (and thus, reactive molecular iodine) would be included in this category. Thus, it would have been prima facie obvious to include the iodide ions in the second hydrogel layer, rendering claim 8 obvious.

10. Zinc salts have long been known to have a stabilizing effect on hydrogen peroxide. For instance, Barrows discloses gel compositions comprising hydrogen peroxide that is stabilized by various zinc salts, including zinc lactate (abstract; column 3, lines 13-27; claims 1 and 6). Thus, the skilled artisan would have been motivated to

include a source of zinc ions in order to inhibit degradation of the reactive hydrogen peroxide generated by the glucose oxidase, per the teachings of Barrows. In doing so, the ordinary artisan would have had a high expectation of providing a dressing composition wherein the antibacterial effect of the hydrogen peroxide is increased since there would be expected to be higher levels of hydrogen peroxide in the dressing due to the stabilizing effect of the zinc ions. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a zinc source per the teachings of Barrows to stabilize the hydrogen peroxide generated by the glucose oxidase. Therefore claims 9 and 10 are rendered obvious over Davis, Munro, and Barrows.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over GALLEY (WO 91/11105; Published Aug. 8 1991) in view of MUNRO (U.S. 2002/0037270; Published Mar. 28, 2002).

11. Galley discloses anti-microbial compositions containing iodide ions, an oxidoreductease enzyme, namely glucose oxidase (i.e. an oxidizing agent), and its corresponding oxidizable substrate, D-glucose (abstract). Galley teaches that iodide anions are included in the compositions in the form of salts, such as potassium iodide and sodium iodide (page 3, lines 17-21). The compositions of the invention are useful materials for skin preparations and wound dressings due to their antibacterial activity (page 11, elements b, g, and h). The compositions provide antibacterial activity through the action of the glucose oxidase enzyme on glucose, which generates hydrogen peroxide (H_2O_2) in the presence of water and oxygen (page 1, lines 16-21). Galley teaches that the compositions may be in the form of water-containing gels (page 8, 2nd paragraph, lines 8-13 and 20-22). It is noted that the instant specification defines a hydrated hydrogel to be an aqueous gel in hydrated form (paragraph [0025]). Thus, the water containing gels of Galley are hydrated hydrogels, and the enzymes contained therein would be hydrated, as would be recognized by the ordinary artisan. The compositions also advantageously incorporate at least one buffering agent to minimize the fall of pH which may otherwise occur after activation of the concentrated composition (page 7, lines 22-26). Galley teaches that the compositions may be provided in the form of two or more physically separated phases in which the glucose oxidase is prevented from coming into contact with D-glucose until immediately prior to

use. For example, the inventive compositions may take the form of two or more pastes or gels which maintain the glucose oxidase and D-glucose in separate phases until the two are combined prior to use (page 8, lines 17-24).

12. Galley does not teach the use of poly 2-acrylamido-2-methylpropane sulphonic acid (polyAMPS) as the hydrophilic polymer material in the compositions, and does not teach the amount of the hydrophilic polymer in the hydrogels.

13. However, the use of polyAMPS in bioadhesive wound dressings was known in the art at the time of the invention. For example, Munro discloses wound dressings comprising hydrogel compositions having bioadhesive properties (paragraph [0001]). Munro teaches that the polymers used in the hydrogel may include water soluble polymers such as poly(2- acrylamido-2-methylpropane-sulphonic acid) or one of its salts and its copolymers (paragraph [0054]). Munro teaches that "...polymerising and crosslinking water soluble monomers in the presence of water soluble polymers, water and polyhydric alcohols produces hydrogel materials with enhance rheological and consequently adhesive properties" (paragraph [0053]). Furthermore, Munro teaches that AMPS is most preferably used as a monomer in the hydrogel compositions (paragraph [0032]). The skilled artisan would have been motivated to use water soluble polymers such as poly(2-acrylamido-2- methylpropane-sulphonic acid) or its salts since they were known as preferred components of hydrogels for wound dressings and because polyAMPS would have enhanced the rheological and adhesive properties of the dressing as taught by Munro. Munro also teaches that the hydrogels of the

invention most preferably include from 25-70% by weight of the polymeric component (paragraphs [0032] and [0036]).

14. While the teachings of Galley would clearly guide the ordinary artisan to formulate the compositions as hydrogels, Galley does not explicitly describe the particular species of materials useful in the invention to a significant degree. Thus, the ordinary artisan would have looked to the literature for guidance regarding the particular species of materials useful in the invention. Based on these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select a polymeric material comprising polyAMPS, and to use the polymeric material at a level of at least 30% by weight of the gel per the teachings of Munro to provide a suitable hydrogel dressing with enhanced rheological and adhesive properties. Thus, Galley and Munro render claims 1, 2, 4, and 11-13 obvious.

15. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the hydrogel material of Galley as either a layer (e.g. a sheet or film layer within a more structured patch system). It is well within the purview of the ordinary artisan to select the best means of application for a wound dressing composition depending on the particular wound to be treated. Galley teaches the compositions as gels (i.e. an amorphous form) (page 8, lines13 and 22; page 10, line 26), and teaches their use in wound dressings comprising impregnated materials (page 11, element g), suggesting the configuration of the hydrogel as a layer or sheet, as is typical in such preparations. Claim 3 is obvious over Galley and Munro.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galley in view of Munro as applied to claims 1-4 and 11-13 above, and further in view of MUNRO (WO 01/96422; Published Dec. 20, 2001) (hereinafter WO '422).

16. The teachings of Galley and Munro are presented *supra*. Galley does not teach the use of ammonium poly-AMPS.

17. While neither Galley nor Munro teaches the use of ammonium poly-AMPS, WO '422, discloses methods of producing the hydrogel compositions of Munro ('270). WO '422 teaches that preferable monomers of the hydrophilic hydrogel material include ammonium and sodium salts of AMPS.

18. It is noted that there is no evidence of record regarding the criticality of the instantly claimed percentages. Thus, in the absence of evidence to the contrary, it would have been routine optimization for the artisan to vary the amounts of polyAMPS salts, which were taught in the art, to arrive at the most suitable combination, guided by the teachings of Galley, Munro, and WO '422. Thus, claims 5 and 8 are obvious over Davis, Munro, and WO '422.

19. Galley teaches that D-glucose is present most preferably in a weight concentration of at least 0.2% (page 4, line 27), and exemplifies glucose in weight % ranges from 0.5-40%, depending on the type of composition produced (see Examples 32, 35, 40, 43, and 48). Additionally, Galley teaches that suitable glucose precursors may be used alone or along with glucose to advantageously support more sustained antimicrobial activity (page 4, lines 33-36). One of ordinary skill in the art would readily recognize from this teaching that the availability (i.e. the amount) of glucose correlates

with the amount of hydrogen peroxide generated. Thus, the ordinary artisan would be motivated to optimize the amount of glucose in the dressing compositions depending on the particular application and intended length of time for its use. For instance, dressings for more serious or chronic wounds might require more glucose to achieve a longer period of hydrogen peroxide generation than those intended for minor wounds requiring less hydrogen peroxide. The artisan would initially be guided by the range of glucose taught by Galley. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to produce a dressing composition comprising from 2.5-20% glucose as suggested by Galley, rendering claims 6 and 7 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galley in view of Munro and WO '422 as applied to claims 5-8 above, and further in view of BARROWS (U.S. 5,372,802; Issued Dec. 13, 1994).

20. The teachings of Galley, Munro, and WO '422 are presented *supra*. While Galley teaches the use of zinc ions in the hydrogel compositions, the teaching does not provide a sufficient motivation for an ordinary artisan to intentionally include a distinct source of zinc ions.

21. However, Zinc salts have long been known to have a stabilizing effect on hydrogen peroxide. For instance, Barrows discloses gel compositions comprising hydrogen peroxide that is stabilized by various zinc salts, including zinc lactate (abstract; column 3, lines 13-27; claims 1 and 6). Thus, the skilled artisan would have been motivated to include a source of zinc ions in order to inhibit degradation of the reactive hydrogen peroxide generated by the glucose oxidase, per the teachings of Barrows. In doing so, the ordinary artisan would have had a high expectation of providing a dressing composition wherein the antibacterial effect of the hydrogen peroxide is increased since there would be expected to be higher levels of hydrogen peroxide in the dressing due to the stabilizing effect of the zinc ions. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a zinc source per the teachings of Barrows to stabilize the hydrogen peroxide generated by the glucose oxidase. Therefore claims 9 and 10 are rendered obvious over Galley, Munro, WO '422, and Barrows.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject

matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 11/044,715

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 11/044,715 in view of MARTIN (U.S. 5,652,274; Issued Jul. 29, 1997) and MUNRO (WO 01/96422; Published Dec. 20, 2001) (hereinafter WO '422). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '715 claims renders obvious that of the instant claims. The difference between the two claim sets is that instant claims do not recite a

source of lactate ions and the '715 claims do not recite ammonium poly-AMPS. However, the inclusion of lactate as a component of skin dressings was well-known in the art at the time of the invention. For example, Martin discloses therapeutic wound healing compositions for protecting and resuscitating mammalian cells (abstract) and are suitable as pharmaceutical appliances and topical vehicles such as dressings, which include topical gel formulations (column 42, lines 17-28 and 40). These compositions comprise lactate ions, including sodium lactate and zinc lactate (column 30, line 62 to column 31, line 7), which are well a well-known buffering agents and antioxidants. Martin teaches that the antioxidant activity of lactate makes it beneficial in wound dressings due to its ability to reduce injury to mammalian cells or increase the resuscitation rate of mammalian cells (column 30, lines 58-61; column 31, lines 10-14). Furthermore, WO '422 teaches ammonium poly-AMPS as described *supra*. Thus, the entire scope of the instant claims is rendered obvious.

No assignment data is available for the instant application.

U.S. Patent Application No. 10/512,440

Claims 1-4 and 11-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 5-13, 18-22, 24, and 25 of copending Application No. 10/512,440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '440 claims renders obvious that of the instant claims. The difference between the two claim sets is the specification of packaging in the '440 claims. However, the sterile packaging as claimed would have been obvious to an ordinary

artisan. The other elements of the instant claims are taught by the '440 claims. Thus, the entire scope of the instant claims is rendered obvious.

Claims 1-4 and 11-13 are directed to an invention not patentably distinct from claims 2, 5-13, 18-22, 24, and 25 of commonly assigned 10/512,440. Specifically, the packaging elements of the '440 claims would have been obvious to one skilled in the art at the time of the invention.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/512,440, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

U.S. Patent Application No. 10/587,420

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/587,420 in view of MARTIN (U.S. 5,652,274; Issued Jul. 29, 1997) and MUNRO (WO 01/96422; Published Dec. 20, 2001) (hereinafter WO '422). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '420 claims renders obvious that of the instant claims. The difference between the two claim sets is that instant claims do not recite a source of lactate ions and the '420 claims do not recite ammonium poly-AMPS. However, the inclusion of lactate as a component of skin dressings was well-known in the art at the time of the invention. For example, Martin discloses therapeutic wound healing compositions for protecting and resuscitating mammalian cells (abstract) and are suitable as pharmaceutical appliances and topical vehicles such as dressings, which include topical gel formulations (column 42, lines 17-28 and 40). These compositions comprise lactate ions, including sodium lactate and zinc lactate (column 30, line 62 to column 31, line 7), which are well a well-known buffering agents and antioxidants. Martin teaches that the antioxidant activity of lactate makes it beneficial in wound dressings due to its ability to reduce injury to mammalian cells or increase the resuscitation rate of mammalian cells (column 30, lines 58-61; column 31, lines 10-14). Furthermore, WO '422 teaches ammonium poly-AMPS as described *supra*. Thus, the entire scope of the instant claims is rendered obvious.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643